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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/991,480 | 11/09/2001 | Jean Toma | CIBT-P06-120 | 4573 |
| 21559 | 7590 | 06/21/2005 | EXAMINER | |
| CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110 | | | GAMETT, DANIEL C | |
| | | ART UNIT | | PAPER NUMBER |
| | | 1647 | | |

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------|--------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/991,480 | TOMA ET AL. | |
| | Examiner | Art Unit | |
| | Daniel C. Gamett | 1647 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 April 2005.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 30, 31, 33, 35, 36, 38, 64-76, 78, 80 and 82-88 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 30, 31, 33, 35, 36, 38, 64-76, 78, 80, and 82-88 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____

5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

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DETAILED ACTION

1. The amendments of 04/18/2005 have been entered in full. Claims 32, 34, 37, 77, 79, and 81 are cancelled. Claims 30, 31, 33, 35, 36, 38, 64-76, 78, 80, and 82-88 are under examination.

Claim Rejections Withdrawn

2. Rejections of claims 32, 75, 78, 79, and 81-83 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite (sections 10-11 of the Office Action of 10/15/2004), have been obviated by applicant's amendment or rendered moot by the cancellation of claims and are hereby withdrawn.
3. Rejection of claims 30-38, 65, 66-80, and 82-84 under 35 U.S.C. 102(e) as being anticipated by Weiss *et al.*, U.S. Patent 5851822, are withdrawn in view of Applicant's persuasive argument, supported by Exhibits A and B, regarding expression of fibronectin by neural stem cells.

Claim Rejections Maintained - 35 USC § 112

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. Claims 30, 31, 33, 35, 36, 38, 64-76, 78, 80, and 82-88 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement as set forth in the Office Action of 10/15/2004. While the amended claims no longer explicitly recite 'treatment' it remains clear that the intended utility of 'introducing stem cells into a patient' is for the purpose of therapy or treatment. Independent claims 30 and 69 recite "a patient with cell damage or disease" as the recipient of stem cells. Dependent claims 33, 35, 68, 73,

74, 76 recite disease conditions and claims 38, 80, and 87 specifically recite human patients. For what purpose are these patients receiving stem cells, if not for treatment? As stated in the prior office action, the specification discloses examples in which transplanted cells survived and differentiated intact animals but there was no indication that the recipients of the transplanted cells derived any benefit or amelioration of symptoms. Thus, the specification teaches introducing stem cells for research purposes but does not enable treatment of disease. Therefore, the rejection for lack of enablement set forth in the prior office action must be maintained with the inclusion of new dependent claims 85-88.

Conclusion

6. No claims are allowed.
7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel C Gamett, Ph.D., whose telephone number is 571 272 1853. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571 272 0961. The fax phone number for the organization where this application or proceeding is assigned is 571 273 8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DCG
Art Unit 1647
20 June 2005

Brenda Brumback
BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600